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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Robert E Click

Paralab I

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EXAMINER

MACAULEY, SHERIDAN R

ART UNIT

PAPER NUMBER

1651

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/516,640	Applicant(s) CLICK, ROBERT E	
	Examiner SHERIDAN R. MACAULEY	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 26-29 and 31-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26 and 31-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/22/2006, 3/31/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A response and amendment were received and entered on March 9, 2009. New claims 31-40 have been added. Claims 16-25 and 30 are cancelled. Claims 1-15, 26-29 and 31-40 are pending.

Election/Restrictions

Applicant's election with traverse of Group IX, as set forth in the restriction requirement mailed on June 18, 2008, in the reply filed on March 9, 2009 is acknowledged. Applicant's traversal is on the grounds that there is a special technical feature that is common to the groups, specifically that nonelected Groups I-IV require a common special technical feature. This is not found persuasive because the technical feature that is common to the elected invention and all other groups is a bacterium or fragment thereof of the genus *Dietzia*. However, bacteria of this genus were known in the art at the time of the invention, as taught by Rainey et al. (International Journal of Systematic Bacteriology, 1995, 45:32-36; document cited in IDS). Therefore, there is no special technical feature that is common to the groups that makes a contribution over the prior art. Although applicant argues that there is a special technical feature common to the inventions of Groups I-IV, specifically that the strain of bacteria common to the groups makes a contribution over the prior art, it is noted that this traversal is only with respect to nonelected invention(s); it will therefore be considered in any subsequent or pending divisional applications. It is further noted that the species election requirement made in the restriction requirement mailed on June 18, 2008 between the species of

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components has been withdrawn due to the results of the search. The restriction requirement with respect to the elected invention is deemed proper and is therefore made FINAL.

1. Claims 1-15 and 27-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected groups, there being no allowable generic or linking claim.
2. Claims 26 and 31-40 are examined on the merits in this office action.

Claim Rejections - 35 USC § 112

3. Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim recites a composition comprising a bacterium that is deposited at the American Type Culture Collection as accession number PTA-4125.
4. The invention appears to employ a specific strain of bacteria. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.
5. It appears that a deposit was made in this application as filed as noted on page 4 of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide

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assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 26 and 38-40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite a composition comprising a bacterium of the genus *Dietzia*, or some fragment thereof. Bacteria of the genus recited in the claims are found in nature, i.e. in natural compositions, as evidenced by Duckworth et al. (Extremophiles, 1998, 2:359-366; document cited in IDS), who teach a strain of *Dietzia* found in a natural soda lake. The claims do not recite the composition to be isolated or in some way separate from the natural environment. Therefore, the claims read on a product of nature and are thus directed to non-statutory subject matter.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 26 and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishimaki et al. (US 5,989,892), as evidenced by Rainey et al. (International Journal of Systematic Bacteriology, 1995, 45:32-36; document cited in IDS). The claims recite a

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composition comprising a pharmacologically active dose of a bacterium of the genus *Dietzia*, and active thereof or a protein secreted therefrom, such that the dose is capable of reducing or preventing symptoms of a disease or syndrome whose causative agent is a mycobacterium.

10. Nishimaki teaches compositions comprising bacteria of the species *Rhodococcus maris* (col. 8, lines 37-47). *Rhodococcus maris* was renamed *Dietzia maris*, as taught by Rainey (abstract). Therefore, the reference teaches compositions comprising bacteria of the genus *Dietzia*, which would perform the function recited in the claims.

11. Note that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

12. Therefore, the reference anticipates the cited claims.

13. Claims 26 and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Duckworth et al. (Extremophiles, 1998, 2:359-366; document cited in IDS). The claims recite a composition comprising a pharmacologically active dose of a bacterium of the genus *Dietzia*, and active thereof or a protein secreted therefrom, such that the dose is capable of reducing or preventing symptoms of a disease or syndrome whose causative agent is a mycobacterium.

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14. Duckworth teaches a strain of *Dietzia* found in a natural soda lake and compositions comprising the isolated strain (abstract), which would perform the function recited in the claims.

15. Therefore, the reference anticipates the cited claims.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. Claims 26 and 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alkemade et al. (US 6,139,844) in view of Mosser (WO 99/05304) and Rainey et al. (International Journal of Systematic Bacteriology, 1995, 45:32-36; document cited in IDS). The claims recite a composition comprising a pharmacologically active dose of a bacterium of the genus *Dietzia*, and active thereof or a protein secreted therefrom, such that the dose is capable of reducing or preventing symptoms of a disease or syndrome

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whose causative agent is a mycobacterium. The claims further recite that the composition comprises an animal feed comprising various components and a feed additive, such as a vitamin, mineral, protein supplement or drug. The claims further recite that the composition is incorporated into a dosage form such as a tablet comprising various components.

19. Alkemade teaches the compositions comprising components of bacteria of the Actinomycetales, such as *Rhodococcus* or *Nocardia*, for administration to animals (col. 2, lines 36-60). Alkemade teaches that such compositions may be prepared in various formulations, such as a tablet that contains a base (e.g., powder), disintegrator (e.g. dispersing agent), absorbent, binder and lubricant (col. 6, line 54-col. 7, line 5). The reference teaches that the compositions may be formulated for oral administration, such as in a lozenge, which would comprise an edible product such as those recited in the claims and a mineral such as a salt (col. 7, lines 6-31). The reference does not specifically teach the use of a species of the genus *Dietzia*.

20. Mosser teaches the preparation of strains of *Rhodococcus* for use in eliciting an immune response that may be an active *Rhodococcus* cell or an immunogenic fragment thereof, such as a protein (abstract, p. 8, lines 4-14; p. 12, lines 10-21).

21. Rainey teaches that members of the genus *Dietzia* are closely related to *Rhodococcus* and were once considered to be in the same genus (p. 359).

22. At the time of the invention, bacteria of the Actinomycetales, such as *Rhodococcus*, were known to be useful in compositions for the administration to animals, as taught by Alkemade and Mosser. At the time of the invention, species of the

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genus *Dietzia* were known to be closely related to and sometimes synonymous with *Rhodococcus*. Although none of the references specifically teach compositions comprising bacteria of the genus *Dietzia*, Alkemade and Mosser teach that one would have a reasonable expectation of success in selecting any species of *Rhodococcus* or related organisms for the preparation of compositions such as those recited in the claims. One would therefore have been able to choose from the finite number of identified, predictable species of bacteria for the preparation of such claims, *Rhodococcus maris* (i.e. *Dietzia maris*) being one of them. One would therefore have been motivated to practice and would have had a reasonable expectation of success in practicing the claimed invention. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

23. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/
Primary Examiner, Art Unit 1651